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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,174	10/29/2003	Swaminathan Jayaraman	795-A03-004	7393

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EXAMINER	
GHERBI, SUZETTE JAIME J	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,174	JAYARAMAN, SWAMINATHAN	
	Examiner	Art Unit	
	Suzette J Gherbi	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-14,16,18-22 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-14,16,18-22 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's RCE and amendment dated 6/17/05 has been received in application serial number 10/696,174. Claims 3-4, 15, 17, and 23-25 have been canceled.

Claim Objections

2. Claim 5 is objected to because of the following informalities: Claim 5 should depend from a preceding claim i.e. should depend from claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-2, 12, 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Francis et al. 6,524,795. Francis et al. discloses the invention as claimed comprising: a method for treating a patient with an intravascular implant by diagnosing

the patient as having a vascular disease; determining a prevalent disease process in the pathology of the vascular disease; selecting a first agent to treat or prevent the prevalent disease process of the vascular disease; coating at least a portion of the implant with a therapeutically effective amount of the first agent; wherein the disease process is determined using genetic determination to identify differently expressed genes in the disease process (see col. 2, lines 65-67, col. 5, lines 59-65); wherein the intravascular implant is a stent or graft (col. 8, lines 41, col. 25, lines 5-28).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6, 8-11, 13-14, 16 and 20-22, 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et al in view of Falotico et al. 2003/0060877. Francis et al. has been disclosed above as providing the methods of diagnosing a process of a vascular disease by utilizing genetic determination to identify differently expressed genes however Francis et al. does not specify the methods of selecting a second agent and coating at least a portion of the implant with a therapeutically effective amount of the second agent; or that the polymer matrix is bio-absorbable. Falotico et al. teaches selecting a first agent to treat or prevent the disease; coating a

portion of the intravascular implant with an effective amount of the first agent; then utilizing a second agent to treat or prevent the vascular disease by applying it to the implant (see [0032]); identifying using an MRI or other devices [0026]; wherein an agent is a calcium [0012]; wherein a polymer matrix (biodegradable) is utilized [0201]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the kit and methods of Francis which diagnosis cardiovascular disorders and apply therapeutics to an intravascular implant and coat the device with first and second agents as a way of treating multiple infarctions with a cocktail of drugs. It also would have been obvious to utilize a bioabsorbale polymer because it is well known in the art that the bioabsorbables release the drugs at varying rates into vascular system and are then expelled by the body.

7. Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Francis et al. in view of Strecker 6,193,746. Francsis is discloses the methods as claimed however Francis does not specify that coating the implant be performed at the procedure site. Strecker (see col. 4, lines 32-67) teaches a stent that is capable of providing medications by tubes located uniformly around the lining for distribution around the circumference of the stent which equates to *coating a stent at the procedure site* because the tube can be attached to and detached to the implant once enough medication is supplied (see col. 4, lines 44-67 and col. 6, l lines 45-50). It would have been obvious to one having ordinary skill in the art at the time the invention was made to take the diagnostic procedures and kit of Francis and utilize a procedure such as

Streckers in order to coat the implant at the procedure because implant of Francis is not limited to the stent structure and by adding the tubing of Strecker to an implant device would allow for the surgeon/technician to administer the agents in a liquid form thereby coating at the procedure site.

Response to Arguments

10. Applicant's arguments filed 16/17/05 have been fully considered but they are not persuasive. Applicant has amended the claims to add such limitations of diagnosing the patient as having a vascular disease; and identifying differently expressed genes in the disease process. In view of these changes the Francis et al. reference disclosed above has been applied and Francis does discloses the "process" for diagnosing a patient having a vascular disease and uses genetic determination to identify the differently expressed genes (i.e. see col. 5, lines 59-65 which states *"thus IL-1 genes are reasonable for determining art of the genetic susceptibility to inflammatory diseases* ..."). The office action of Francis in view of Falotico et al. patent is deemed proper because Falotico et al teaches combining more than one agent to treat vascular disorders along with a combination of different types of drugs and polymers. In conclusion the new rejection in response to the amendment is proper because Francis et al. main invention is to diagnosis disorders of vascular diseases within individuals and epidemiologic studies that indicated an individuals genetic composition (col. 2,lines

66-67) and the patent discloses varying genetic make-up has diversified effected with regards to cardiovascular disorders.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Repeto EP 1262 153 also discloses that pharmaceutical compositions for a delivery on site.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 571-272-4751.

13. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Suzette J-J Gherbi
24 June 2005